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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,228	03/27/2001	Kent L. Christopher	1246/39(a)	2216

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EXAMINER	
PATEL, MITAL B	
ART UNIT	PAPER NUMBER
3761	18

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,228	CHRISTOPHER, KENT L.	
	Examiner	Art Unit	
	Mital B. Patel	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. In view of the Appeal Brief filed on 4/4/03, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 6, 8, 11-15, 20, 23, 25 and 28are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi (US 6394093).

4. **As to claim 1**, Lethi teaches a nasopharyngeal catheter for open delivery of a continuous air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, the nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration; a delivery tube **9** adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

5. **As to claim 2**, Lethi teaches a nasopharyngeal catheter wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

6. **As to claim 6**, Lethi teaches essentially all of the limitations except for a connector for removably attaching the proximal end of the nasal catheter to the delivery

tube. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device.

7. **As to claim 8**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of approximately 3 mm. Applicant has not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

8. **As to claim 11**, Lethi teaches essentially all of the limitations except for wherein gas is supplied through the nasal catheter at a back pressure of approximately 2 to 25 psi. However, Applicant has not stated how the particular back pressure solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the pressure would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a back pressure within the range of 2 to 25 psi based on the intended use, intended patient, and intended therapy.

9. **As to claims 12**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises oxygen.

10. **As to claims 13**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises air.

11. **As to claim 14**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

12. **As to claim 15**, Lethi teaches a nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration; the catheter being made of flexible material that can be trimmed to a desired length; a delivery tube **9** adapted to extend below the patient's nostril having a connector for attachment to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a removable connector. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem

or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

13. **As to claim 20**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of approximately 3 mm. Applicant has not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

14. **As to claim 23**, Lethi teaches a method for providing a supplemental continuous flow of air/oxygen to a spontaneously breathing patient, the method comprising advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration. It should be noted that Lethi fails to specifically teach the step of supplying air/oxygen through the catheter at a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record

or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

15. **As to claim 25**, Lethi teaches essentially all of the limitations except for the initial step of selecting the length of the catheter by advancing a catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula. However, it would be obvious to one of ordinary skill in the art to include this initial step since the length of the catheter will differ from individual to individual. Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

16. **As to claim 28**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

17. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Bowden et al (US 6374827).

18. **As to claims 3 and 16**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter. However, Bowden does teach a plurality of markings for a variety of positions for different sized patients or children and for determining proper insertion. Therefore, it would be obvious to one of ordinary skill in the art to modify the catheter of Lethi to include a plurality of markings as taught by Bowden for a variety of positions for different sized patients or children and for determining proper insertion.

19. Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Brain (US 6055984).

20. **As to claims 4 and 17**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter comprises a radio-opaque stripe. However, Brain does teach the use of a radio-opaque stripe to allow for easy identification of the location of a tube. Therefore, it would be obvious to one of ordinary skill to modify the catheter of Lethi to include a radio-opaque stripe as taught by Brain stripe to allow for easy identification of the location of the catheter.

21. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Dali et al (US 3682171).

22. **As to claim 5**, Lethi teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to

the gas source. Lethi fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source. Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of Dali et al. in Lethi's catheter to cap the connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

23. **As to claim 18**, Lethi teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to the gas source. Lethi fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source. Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of Dali et al. in Lethi's catheter to cap the connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

24. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Spofford et al (US 5297546).

25. **As to claim 7**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and

subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

26. **As to claim 19**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

27. Claims 9, 10, 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Daniell et al (US 6050260).

28. **As to claim 9**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

29. **As to claim 10**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

30. **As to claim 21**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

31. **As to claim 22**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

32. **As to claim 26**, Lethi teaches essentially all of the limitations except for the method further comprising controlling the humidity of the air/oxygen supplied through the catheter. However, Daniell teaches the method of controlling the humidity of the gas delivered through the nasal catheter in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to include the method of Daniell for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

33. **As to claim 27**, the above combination teaches a method regulating the temperature of air/oxygen supplied through the catheter.

34. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Linder et al (US 3957055)

35. **As to claim 24**, Lethi teaches essentially all of the limitations except for cutting the proximal end of the catheter to a desired length so that the distal tip of the catheter will have a desired position relative to the patient's uvula and attaching the proximal end of the catheter to the connector on the delivery tube. However, Linder does teach the step of cutting a tube to the approximate length prior to use and then attaching the connector on the tube. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Lethi to include cutting the tube so that a desired length is acquired prior to use.

Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 3499450.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
June 5, 2003

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